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and Lupin Ltd.*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ORTHO-MCNEIL PHARMACEUTICAL, INC.,)	
ORTHO-MCNEIL, INC., and DAIICHI)	DOCUMENT ELECTRONICALLY
PHARMACEUTICAL CO., LTD.)	FILED
)	
Plaintiffs,)	Civ. Action No. 3:06cv04999
)	
v.)	Chief District Judge
)	Garrett E. Brown, Jr.
LUPIN PHARMACEUTICALS, INC., and)	
LUPIN LTD.)	Magistrate Judge
)	Tonianne J. Bongiovanni
Defendants.)	

LUPIN PHARMACEUTICALS, INC., and)
LUPIN LTD.)
)
Counterclaim-Plaintiffs,)
)
v.)
)
ORTHO-MCNEIL PHARMACEUTICAL, INC.,)
ORTHO-MCNEIL, INC., and DAIICHI)
PHARMACEUTICAL CO., LTD.)
)
Counterclaim-Defendants.)

ANSWER, AFFIRMATIVE DEFENSE AND COUNTERCLAIM

Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd
(collectively "Lupin") hereby respond to the Complaint of

Plaintiffs, Ortho-McNeil Pharmaceutical, Inc. ("OMP"), Ortho-McNeil, Inc. ("OMI"), and Daiichi Pharmaceutical ("Daiichi") (collectively "Plaintiffs") as follows:

1. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 and therefore denies such allegations.

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and therefore denies such allegations.

3. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore denies such allegations.

4. Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202 and is registered to do business in New Jersey and has appointed the National Registered Agents Inc. of Princeton, New Jersey as its registered agent in New Jersey for service of process. Lupin further admits that Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Ltd. Lupin denies the remaining allegations in paragraph 4.

5. Lupin admits that Lupin Ltd. is an Indian corporation having a place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai, 400 051, India. Lupin further admits that Lupin Ltd. manufactures generic drugs. Lupin denies the remaining allegations in paragraph 5.

6. Lupin admits that Plaintiffs purport to bring Count 1 of this action under Title 35, United States Code for infringement of U.S. Patent No. 5,053,407 ("the '407 patent") and that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

7. Lupin does not contest personal jurisdiction for purposes of the present action only. Lupin denies the remaining allegations in paragraph 7.

8. Lupin does not contest personal jurisdiction for purposes of the present action only. Lupin denies the remaining allegations in paragraph 8.

9. Lupin does not contest personal jurisdiction for purposes of the present action only. Lupin denies the remaining allegations in paragraph 9.

10. Lupin does not contest venue for purposes of the present action only.

11. Lupin re-asserts its responses to paragraphs 1-10 as if fully set forth herein.

12. Lupin admits that a copy of the '407 patent, entitled "Optically Active Pyridobenzoxazine Derivatives and Anti-Microbial Use," was attached to the Complaint as Exhibit A. Lupin Ltd. further admits that the issue date set forth on the face of the '407 patent is October 1, 1991. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 12 of the Complaint and, therefore, denies such allegations.

13. Lupin admits that the '407 patent is assigned on its face to Daiichi. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 13 of the Complaint and, therefore, denies such allegations.

14. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 14 of the Complaint and, therefore, denies such allegations.

15. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 15 of the Complaint and, therefore, denies such allegations.

16. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 16 of the Complaint and, therefore, denies such allegations.

17. Lupin admits that Lupin Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 78-424 to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell levofloxacin tablets (250 mg, 500 mg, and 750 mg) before the expiration of the '407 patent term extension as listed in the FDA Orange Book. Lupin denies the remaining allegations in paragraph 17.

18. Lupin admits that Lupin Ltd.'s letter, which was dated September 29, 2006 and received on October 2, 2006 by Plaintiffs OMP and Daiichi states that Lupin Ltd. filed ANDA 78-424 seeking

approval to manufacture, use or sell levofloxacin tablets (250 mg, 500 mg, and 750 mg). Lupin further admits that Lupin Ltd.'s letter states that ANDA 78-424 contains a Paragraph IV certification that Lupin Ltd.'s manufacture, use or sale of levofloxacin tablets (250 mg, 500 mg, and 750 mg) will not infringe the claims of the '407 patent. Lupin denies the remaining allegations in paragraph 18.

19. Lupin admits that Lupin Ltd. is subject to 35 U.S.C. § 271(e)(2)(A) as a result of Lupin Ltd.'s filing ANDA 78-424. Lupin denies the remaining allegations of paragraph 19.

20. Lupin denies the allegations of paragraph 20.

21. Lupin denies the allegations of paragraph 21.

22. Lupin denies the allegations of paragraph 22.

23. Lupin denies the allegations of paragraph 23.

24. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 24 of the Complaint and, therefore, denies such allegations.

25. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint and, therefore, denies such allegations.

26. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 26 of the Complaint and, therefore, denies such allegations.

27. Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202 and is registered to do business in New Jersey and has appointed the National Registered Agents Inc. of Princeton, New Jersey as its registered agent in New Jersey for service of process. Lupin further admits that Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Ltd. Lupin denies the remaining allegations in paragraph 27.

28. Lupin admits that Lupin Ltd. is an Indian corporation having a place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai, 400 051, India. Lupin further admits that Lupin Ltd. manufactures generic drugs for sale and use in the United States, including in this judicial district. Lupin denies the remaining allegations in paragraph 28.

29. Lupin admits that Plaintiffs' declaratory judgment claim is pursuant to the Declaratory Relief Act and the Patent Laws of the United States to declare the legal rights of the parties. Lupin further admits that an actual, justiciable controversy exists between it and Plaintiffs based on Lupin Ltd.'s filing of ANDA No. 78-424. Lupin denies the remaining allegations in paragraph 29.

30. Lupin admits that this Court has jurisdiction over the subject matter of Plaintiffs' declaratory judgment claim under 28 U.S.C. §§ 1391 and 1338(a).

31. Lupin does not contest personal jurisdiction for purposes of the present action only. Lupin denies the remaining allegations in paragraph 31.

32. Lupin does not contest personal jurisdiction for purposes of the present action only. Lupin denies the remaining allegations in paragraph 32.

33. Lupin does not contest personal jurisdiction for purposes of the present action only. Lupin denies the remaining allegations in paragraph 33.

34. Lupin does not contest venue for purposes of the present action only.

35. Lupin re-asserts its responses to paragraphs 1-34 as if fully set forth herein

36. Lupin admits that a copy of the '407 patent, entitled "Optically Active Pyridobenzoxazine Derivatives and Anti-Microbial Use," was attached to the Complaint as Exhibit A. Lupin Ltd. further admits that the issue date set forth on the face of the '407 patent is October 1, 1991. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 12 of the Complaint and, therefore, denies such allegations.

37. Admitted

38. Lupin admits that Lupin Ltd. submitted ANDA No. 78-424 to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell levofloxacin tablets (250 mg, 500 mg, and 750 mg) before the expiration of the '407 patent term

extension as listed in the FDA Orange Book. Lupin denies the remaining allegations in paragraph 38.

39. Lupin admits that Lupin Ltd.'s letter, which was dated September 29, 2006 and received on October 2, 2006 by Plaintiffs OMP and Daiichi states that Lupin Ltd. filed ANDA 78-424 seeking approval to manufacture, use or sell levofloxacin tablets (250 mg, 500 mg, and 750 mg). Lupin further admits that Lupin Ltd.'s letter challenges the validity of the '407 patent term extension. Lupin denies the remaining allegations in paragraph 39.

40. Admitted.

41. To the extent that paragraph 41 sets forth any factual allegations, Lupin denies the same.

AFFIRMATIVE DEFENSE

Without prejudice to the denials set forth in its Answer, Lupin alleges the following affirmative defense to the Complaint.

42. The certificate issued by the United States Patent and Trademark Office on March 10, 2000 for the '407 patent, allegedly under the provisions of 35 U.S.C. § 156, is invalid.

43. The commercial manufacture, use, sale, offer for sale or importation of Lupin Ltd.'s levofloxacin tablets as set forth in Lupin Ltd.'s ANDA No. 78-424 would not, when marketed after October 1, 2008, infringe any valid and/or enforceable claim of the '407 patent.

REQUESTED RELIEF

WHEREFORE, Lupin prays for the following:

A. Judgment that Plaintiffs are entitled to none of the relief requested in its Complaint and judgment for Lupin and an order dismissing the complaint with prejudice;

B. A judgment and order declaring that the manufacture, use, sale, offer for sale, or importation of Lupin Ltd.'s levofloxacin tablets that are the subject of Lupin Ltd.'s ANDA No. 78-424 would not, when marketed after October 1, 2008, infringe any valid and/or enforceable claim of the '407 patent;

C. A judgment and order declaring that the certificate issued by the United States Patent and Trademark Office on March 10, 2000 for the '407 patent, allegedly under the provisions of 35 U.S.C. § 156, is invalid.

D. Attorneys fees as allowed by law;

E. Costs and expenses in this action; and

F. Such further relief as this Court may deem just and proper.

COUNTERCLAIM

THE PARTIES

1. Counterclaim-Plaintiff Lupin Ltd. is an Indian corporation having a place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai, 400 051, India.

2. Counterclaim-Plaintiff Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of the Commonwealth of Virginia having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

3. Based upon the allegations in the complaint in this case, Counterclaim-Defendant Ortho-McNeil Pharmaceutical, Inc. ("OMP") is a wholly owned subsidiary of Johnson & Johnson and is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1000 U.S. Route 202, Raritan, New Jersey, 08869.

4. Based upon the allegations in the complaint in this case, Counterclaim-Defendant Ortho-McNeil, Inc. ("OMI") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1000 U.S. Route 202, Raritan, New Jersey, 08869.

5. Based upon the allegations in the complaint in this case, Counterclaim-Defendant Daiichi Pharmaceutical Co., Ltd. ("Daiichi") is a corporation organized and existing under the laws of Japan, having its principal place of business at 14-10, Nihonbashi 3-chome, Chuo-ku, Tokyo, Japan.

JURISDICTION AND VENUE

6. This counterclaim is an action for a declaratory judgment of invalid extension of patent term and non-infringement arising under the patent laws of the United States, Title 35 of the United States Code.

7. This Court has jurisdiction over the subject matter of this counterclaim under the Declaratory Judgment Act and the Patent Laws of the United States based on 28 U.S.C. §§1331, 1338(a), and 28 U.S.C. §§ 2201 and 2202.

8. Venue properly lies within the District of New Jersey under 28 U.S.C. §§ 1391(c) and 1400(b).

9. On October 16, 2006, Plaintiffs sued Lupin Pharmaceuticals, Inc. and Lupin Ltd. (collectively "Lupin") in this District alleging infringement of United States Patent No. 5,053,407 ("the '407 patent").

10. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and the Counterclaim-Defendants regarding the non-infringement of the '407 patent and the certificate issued by the United States Patent and Trademark Office on March 10, 2000 for the '407 patent, allegedly under the provisions of 35 U.S.C. § 156.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY)

11. Lupin repeats and realleges paragraphs 1 through 10 of the counterclaim, inclusive, as though fully set forth herein and incorporates them by reference.

12. On October 1, 1991, the United States Patent and Trademark Office ("PTO") issued the '407 patent, entitled "Optically Active Pyridobenzoxazine Derivatives and Anti-Microbial Use," to Isao Hayakawa, Shohgo Atarashi, Masazumi Imamura, Shuichi Yokohama, Nobuyuki Higashihashi, Katsuichi Sankano, and Msayuki Ohshima.

13. Based upon the allegations in the complaint in this case, Counterclaim-Defendant Daiichi owns and has the right to enforce the '407 patent.

14. Based upon the allegations in the complaint in this case, Counterclaim-Defendant OMI is the exclusive sublicense under the '407 patent pursuant to an exclusive license agreement between Daiichi and Johnson & Johnson.

15. Based upon the allegations in the complaint in this case, Counterclaim-Defendant OMP is the holder of the approved New Drug Applications ("NDAs") for levofloxacin tablets (250 mg, 500 mg, and 750 mg).

16. Lupin Ltd.'s levofloxacin tablets that are the subject of Lupin Ltd.'s ANDA No. 78-424 would not, when marketed after October 1, 2008, infringe any valid and/or enforceable claim of the '407 patent.

17. Lupin is entitled to a judicial declaration that it would not, when marketed after October 1, 2008, infringe any valid and/or enforceable claim of the '407 patent through the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s levofloxacin tablets that are the subject of Lupin Ltd.'s ANDA No. 78-424.

18. The certificate issued by the United States Patent and Trademark Office on March 10, 2000 for the '407 patent, allegedly under the provisions of 35 U.S.C. § 156, is invalid.

19. Unless the March 10, 2000 certificate for the '407 patent is judged invalid, Lupin will be prohibited from commercially marketing Lupin Ltd.'s levofloxacin tablets that are the subject of Lupin Ltd.'s ANDA No. 78-424 to the detriment of Lupin and the public. As such, Lupin is entitled to a

judicial decision that the certificate to the '407 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Lupin prays for the following:

A. Judgment and order dismissing the complaint with prejudice; and judgment entered in favor of Lupin;

B. A judgment and order declaring that the manufacture, use, sale, offer for sale, or importation of Lupin Ltd.'s levofloxacin tablets that are the subject of Lupin Ltd.'s ANDA No. 78-424 would not, if marketed after October 1, 2008, infringe any valid and/or enforceable claim of the '407 patent;

C. A judgment and order declaring that the certificate issued by the United States Patent and Trademark Office on March 10, 2000 for the '407 patent, allegedly under the provisions of 35 U.S.C. § 156, is invalid;

D. Attorneys fees as allowed by law;

E. Costs and expenses in this action; and

F. Such further relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED,

DATED: February 15, 2007

STERNS & WEINROTH, P.C.

By: /s/ Karen A. Confoy
Karen A. Confoy
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Attorney for Defendant
Lupin Pharmaceuticals,
Inc. and Defendant and
Counterclaim-Plaintiff
Lupin Ltd.